

Exhibit G

1
2
3 IN RE: :SUPERIOR COURT OF
PELVIC MESH/GYNECARE :NEW JERSEY
4 LITIGATION :LAW DIVISION -
:ATLANTIC COUNTY
5 :
:MASTER CASE 6341-10
6 :
:CASE NO. 291 CT

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF
8 CONFIDENTIALITY

September 13, 2012

23 - - -

24 GOLKOW TECHNOLOGIES, INC.

877.370.3377 ph | 917.951.5672 fax

25 deps@golkow.com

1 A. Correct.

2 Q. And it says the potential effect of
3 that is damage to the cannula and the potential
4 hazard what could occur would be tissue damage,
5 correct?

6 A. Correct.

7 Q. And the potential harm that could
8 result here is described as bleeding, correct?

9 A. Correct.

10 Q. And you understood that through your
11 review of this -- rephrase.

12 And you understood that it was
13 required that you capture all of the different
14 failure modes, all the things that could go
15 wrong in the procedure, even if the doctor was
16 properly trained and following the proper
17 procedure, and the effects of those failure
18 modes, the hazards that could occur, and the
19 resulting harms, and you were supposed to
20 capture all of them, correct?

21 A. Yes, all that we could conceive of,
22 yes.

23 Q. Now, one of the things that could
24 happen is during the passage of the guides, is
25 the pudendal nerve could be injured, correct?

1 specifically mentioned in the document.

2 BY MR. SLATER:

3 Q. And therefore, none of them are
4 specifically scored, correct?

5 A. They would have been included in
6 things other than the terms that you mentioned.

7 Q. As the document appears and as it was
8 specifically and carefully written by quality
9 engineering, with your approval, those items do
10 not appear and are not specifically scored,
11 correct?

12 A. Those items are not specifically
13 mentioned, no.

14 Q. All right. Now let's look at the
15 dFMEA, which is Exhibit 629. You understood
16 the purpose of the dFMEA, correct?

17 A. Yes.

18 Q. That's the Design Failure Modes and
19 Effects Analysis, correct?

20 A. Yes.

21 Q. And what was the purpose of this
22 analysis?

23 A. To review the potential risk
24 associated with the design of the product.

25 Q. And when you say "associated with the

1 design of the product," that means that when
2 the product is in a woman's body and the
3 product was manufactured completely consistent
4 with the specifications, these are the things
5 that could go wrong and harm a patient,
6 correct?

7 A. Correct.

8 Q. Let's look now at this dFMEA, and
9 let's look at page -- looking at the Bates
10 number 03573, the actual chart and grid.

11 And it indicates that you were one of
12 the individuals who provided input as medical
13 director, correct?

14 A. Yes.

15 Q. And again, as with the aFMEA, you had
16 to sign off on the dFMEA in order for this gate
17 to be surpassed so the product could move
18 closer to Product Release Authorization and to
19 be marketed to be put in women's bodies,
20 correct?

21 A. Correct.

22 Q. And what this does is, in the chart,
23 is the different components of the PROLIFT kit
24 are each evaluated in terms of what harms they
25 could cause if they were to fail, correct?